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BAUSCH & LOMB INCORPORATED,
BAUSCH & LOMB PHARMA HOLDINGS CORP., and
SENJU PHARMACEUTICAL CO., LTD.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

BAUSCH & LOMB INCORPORATED,)	
BAUSCH & LOMB PHARMA HOLDINGS)	
CORP., and SENJU PHARMACEUTICAL)	
CO., LTD.,)	
)	Civil Action No.:
Plaintiffs,)	
)	
v.)	
)	
APOTEX INC. and APOTEX CORP.,)	
)	
Defendants.)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Bausch & Lomb Incorporated, Bausch & Lomb Pharma Holdings Corp. and Senju Pharmaceutical Co., Ltd. (collectively “Plaintiffs”) by way of Complaint against Defendant Apotex Inc. and Apotex Corp. (collectively, “Apotex”) allege as follows:

THE PARTIES

1. Plaintiff Bausch & Lomb Incorporated (“B+L”) is a corporation organized and existing under the laws of New York, with a place of business at 1400 North Goodman St.,

Rochester, New York 14609. B+L is the registered holder of approved New Drug Application (“NDA”) No. 022288, which covers Bepreve[®].

2. Plaintiff Bausch & Lomb Pharma Holdings Corp. (“B+L Pharma Holdings”) is a corporation organized and existing under the laws of Delaware, with a place of business at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807. B+L Pharma Holdings is a wholly-owned subsidiary of B+L.

3. Plaintiff Senju Pharmaceutical Co., Ltd. (“Senju”) is a corporation organized and existing under the laws of Japan, with a principal place of business at 2-5-8, Hirano-machi, Chuo-ku, Osaka 541-0046, Japan.

4. Upon information and belief, defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

5. Upon information and belief, defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida. Upon information and belief, defendant Apotex Corp. is a wholly-owned subsidiary of defendant Apotex Inc.

NATURE OF THE ACTION

6. This is an action for infringement of United States Patent Nos. 8,784,789 (“the ’789 patent”) and 8,877,168 (“the ’168 patent”), arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Apotex’s filing of an Abbreviated New Drug Application (“ANDA”) under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to market generic bepotastine besilate ophthalmic solution, 1.5% (“Apotex’s generic bepotastine besilate ophthalmic solution”).

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

8. Upon information and belief, this Court has jurisdiction over Apotex Inc. Upon information and belief, Apotex Inc. directly, or indirectly, manufactures, markets and sells generic drug products, including generic drug products manufactured by Apotex Corp., throughout the United States and in this judicial district, and this judicial district is a likely destination for Apotex's generic bepotastine besilate ophthalmic solution. Upon information and belief, Apotex Inc. purposefully has conducted and continues to conduct business in this judicial district.

9. Upon information and belief, this Court has jurisdiction over Apotex Corp. Upon information and belief, Apotex Corp. is in the business of manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, Apotex Corp. directly manufactures, markets and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Apotex's generic bepotastine besilate ophthalmic solution. Upon information and belief, Apotex Corp. purposefully has conducted and continues to conduct business in this judicial district.

10. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

THE PATENT IN SUIT

11. The U.S. Patent and Trademark Office ("PTO") issued the '789 patent on July 22, 2014. The '789 patent generally speaking claims, *inter alia*, aqueous liquid bepotastine preparations. Plaintiffs hold all substantial rights in the '789 patent and have the right to sue for infringement thereof. Senju is the assignee of the '789 patent. A copy of the '789 patent is attached hereto as Exhibit A.

12. The U.S. Patent and Trademark Office (“PTO”) issued the ’168 patent on November 4, 2014. The ’168 patent generally speaking claims, *inter alia*, aqueous liquid bepotastine preparations. Plaintiffs hold all substantial rights in the ’168 patent and have the right to sue for infringement thereof. Senju is the assignee of the ’168 patent. A copy of the ’168 patent is attached hereto as Exhibit B.

13. B+L is the holder of NDA No. 022288 for Bepreve[®], which the FDA approved on September 8, 2009. In conjunction with NDA No. 022288, the ’789 and the ’168 patents are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”).

14. Bepotastine besilate ophthalmic solution is sold in the United States under the trademark Bepreve[®].

APOTEX’S INFRINGING ANDA SUBMISSION

15. Upon information and belief, Apotex Corp. filed with the FDA ANDA No. 206066, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

16. Upon information and belief, Apotex Corp.’s ANDA No. 206066 seeks FDA approval to sell in the United States Apotex’s generic bepotastine besilate ophthalmic solution, intended to be a generic version of Bepreve[®].

17. B+L received a letter from Apotex dated April 23, 2015, purporting to be a Notice of Certification for ANDA No. 206066 (“Apotex’s notice letter”) under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21 § C.F.R. 314.95(c).

18. Apotex’s notice letter alleges that Apotex Corp. has submitted to the FDA ANDA No. 206066 seeking FDA approval to sell generic bepotastine besilate ophthalmic solution, intended to be a generic version of Bepreve[®].

19. Upon information and belief, ANDA No. 206066 seeks approval of Apotex's generic bepotastine besilate ophthalmic solution that is the same, or substantially the same, as Bepreve[®].

20. Upon information and belief, Apotex Corp.'s actions relating to ANDA No. 206066 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of Apotex Inc.

COUNT I

Infringement of the '789 Patent under § 271(e)(2)

21. Paragraphs 1-20 are incorporated herein as set forth above.

22. Under 35 U.S.C. § 271(e)(2), Apotex has infringed at least one claim of the '789 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206066 seeking approval for the commercial marketing of Apotex's generic bepotastine besilate ophthalmic solution before the expiration date of the '789 patent.

23. Upon information and belief, Apotex's generic bepotastine besilate ophthalmic solution will, if approved and marketed, infringe at least one claim of the '789 patent.

24. Upon information and belief, Apotex will, through the manufacture, use import, offer for sale and/or sale of Apotex's generic bepotastine besilate ophthalmic solution, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '789 patent.

COUNT II

Declaratory Judgment of Infringement of the '789 Patent

25. Paragraphs 1-24 are incorporated herein as set forth above.

26. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

27. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

28. Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Apotex's generic bepotastine besilate ophthalmic solution before the expiration date of the '789 patent, including Apotex's filing of ANDA No. 206066.

29. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's generic bepotastine besilate ophthalmic solution will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '789 patent.

30. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's generic bepotastine besilate ophthalmic solution will constitute infringement of at least one claim of the '789 patent.

COUNT III

Infringement of the '168 Patent under § 271(e)(2)

31. Paragraphs 1-30 are incorporated herein as set forth above.

32. Under 35 U.S.C. § 271(e)(2), Apotex has infringed at least one claim of the '168 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206066 seeking approval for the commercial marketing of Apotex's generic bepotastine besilate ophthalmic solution before the expiration date of the '168 patent.

33. Upon information and belief, Apotex's generic bepotastine besilate ophthalmic solution will, if approved and marketed, infringe at least one claim of the '168 patent.

34. Upon information and belief, Apotex will, through the manufacture, use import, offer for sale and/or sale of Apotex's generic bepotastine besilate ophthalmic solution, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '168 patent.

COUNT IV

Declaratory Judgment of Infringement of the '168 Patent

35. Paragraphs 1-34 are incorporated herein as set forth above.

36. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

37. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

38. Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Apotex's generic bepotastine besilate ophthalmic solution before the expiration date of the '168 patent, including Apotex's filing of ANDA No. 206066.

39. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's generic bepotastine besilate ophthalmic solution will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '168 patent.

40. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's generic bepotastine besilate ophthalmic solution will constitute infringement of at least one claim of the '168 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Apotex on the patent infringement claim set forth above and respectfully request that this Court:

1. enter judgment that, under 35 U.S.C. § 271(e)(2), that Apotex has infringed at least one claim of the '789 patent through Apotex's submission of ANDA No. 206066 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Apotex's generic bepotastine besilate ophthalmic solution before the expiration of the '789 patent;

2. enter judgment that, under 35 U.S.C. § 271(e)(2), that Apotex has infringed at least one claim of the '168 patent through Apotex's submission of ANDA No. 206066 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Apotex's generic bepotastine besilate ophthalmic solution before the expiration of the '168 patent;

3. order that the effective date of any approval by the FDA of Apotex's generic bepotastine besilate ophthalmic solution be a date that is not earlier than the expiration of the '789 patent and the '168 patent, or such later date as the Court may determine;

4. enjoin Apotex from the commercial manufacture, use, import, offer for sale and/or sale of Apotex's generic bepotastine besilate ophthalmic solution until expiration of the '789 patent and the '168 patent, or such later date as the Court may determine;

5. enjoin Apotex and all persons acting in concert with Apotex from seeking, obtaining or maintaining approval of Apotex's ANDA No. 206066 until expiration of the '168 patent;
6. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses and disbursements in this action, including reasonable attorneys fees;
7. award Plaintiff such further and additional relief as this Court deems just and proper.

Dated: June 5, 2015

Respectfully submitted,

s/ Melissa A. Chuderewicz
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